Highly Confidential – Subject to Protective Order

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SCIELE PHARMA, INC. *et al.*,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	C.A. No. 09-037 (RBK)(JS)
	)	CONSOLIDATED
LUPIN LTD., *et al.*,	)	
	)	**REDACTED VERSION**
Defendants.	)	
	)	
SHIONOGI PHARMA, INC., *et al.*,	)	
	)	
Plaintiffs,	)	
v.	)	C.A. No. 10-135 (RBK)(JS)
	)	
MYLAN, INC., *et al.*,	)	
	)	
Defendants.	)	

DECLARATION OF IVAN T. HOFMANN, CPA/CFF, CLP

1. I previously submitted a declaration dated April 23, 2012 in connection with this patent infringement case (the "Hofmann Declaration"), as well as a declaration in connection with the preliminary injunction proceedings. In the Hofmann Declaration, I provided opinions as to whether the documents requested by the Plaintiffs and identified in the Declaration of Christopher P. Gerardi, dated March 30, 2012 (the "Gerardi Initial Declaration") were necessary to the determination of damages in this case.[1]

2. I have been asked by counsel to review and respond to the Declaration of Christopher P. Gerardi in Support of Shionogi's Opposition to Lupin's Motion for a Protective Order, dated May 1, 2012 (the "Gerardi Reply Declaration") and Shionogi's Opposition to Lupin's Motion for a Protective Order Concerning Lupin's Allegedly Highly Sensitive Commercial Information Involving Commercial Relationships and Settlement Negotiations, dated May 1, 2012 ("Shionogi's Opposition to Lupin's Motion for a Protective Order"). I have also reviewed the Plaintiffs' Answering Brief in Opposition to Defendants' Motion to Bifurcate Liability and Damages and to Stay Damages Discovery.

Continued Failure to Properly Consider Information Necessary for Damages in this matter

3. The Gerardi Reply Declaration continues to suggest that a "One Size Fits All" approach to document discovery in patent infringement litigation is appropriate. It therefore fails to address properly whether documents are *necessary* to determine damages in this case. Rather, the Gerardi Reply Declaration supports the Plaintiffs' approach to ask for everything regardless of whether the documents and information are necessary and regardless of the potential harm to

[1] See the Hofmann Declaration. My curriculum vitae and cases in which I have testified as an expert at deposition or at trial within the last four years are attached as Appendix 1 and Appendix 2, respectively, to the Hofmann Declaration.

Lupin of being required to produce highly sensitive confidential information to direct competitors, and does not analyze the need to strike a balance between these competing factors.

4. The Gerardi Reply Declaration continues to characterize Shionogi's requests for documents and information as information that is commonly sought in typical patent infringement cases, but does not appropriately consider the specifics of this case and the differences between his experiences in other patent infringement cases and the instant ANDA litigation involving branded and generic companies in the pharmaceutical industry.

5. Shionogi's Opposition to Lupin's Motion for a Protective Order suggests that my previous declaration improperly opines that a different set of standards applies to damages discovery in pharmaceutical patent infringement cases.[2] This is incorrect. I agree that the same basic damages framework for lost profits and reasonable royalty applies to ANDA as well as other patent infringement cases and I did not suggest otherwise. However, the application of this common framework to this case involving ANDA litigation with appropriate consideration of the information *needed* to analyze and quantify damages leads to the conclusion that most of Shionogi's requests for documents and information are overly broad and unnecessary.

6. The Gerardi Reply Declaration generally agrees with many of my opinions regarding the pharmaceutical market, competition among pharmaceutical companies, and the sensitive nature of the information requested.[3] However, it still contends that the documents and information should be produced anyway, without any meaningful justification or explanation as to why the unnecessary information should be produced in this case in light of the potential harm to Lupin from disclosing this highly confidential information to direct competitors.

[2] Shionogi's Opposition to Lupin's Motion for a Protective Order, page 7.
[3] Gerardi Reply Declaration, paragraphs 3c, 3d, 3f, 3g, 3j, 10c, and 14.

7. The Gerardi Reply Declaration repeatedly makes conclusory statements that the production of the documents requested by Shionogi are those that "any prudent independent expert" would want to analyze,[4] but still fails to give a convincing explanation why the "independent expert" would want the information. In fact, many of his assertions relate to documents Lupin has already agreed to produce, including Lupin forecasts and information regarding total net sales and unit sales by dosage strength. In my opinion, the information to be produced by Lupin, along with the information produced by Shionogi and third party data will be sufficient to quantify damages and analyze commercial success.

8. The Gerardi Reply Declaration asserts that many of the types of documents and information requested by Shionogi are needed to analyze the *Panduit* Factors for lost profits and *Georgia-Pacific* Factors to determine a reasonable royalty.[5] However, it does not demonstrate proper consideration or understanding of the market for branded and generic pharmaceutical products. The Gerardi Reply Declaration continues to suggest that Lupin customer information is needed to determine whether Shionogi would have made the sale of the generic product.[6] This position reflects a lack of either understanding or proper consideration of the creation of demand for pharmaceutical products (i.e. prescription writing), the varying distribution networks of pharmaceuticals, United States Food and Drug Administration ("FDA") regulation of prescription pharmaceuticals, and substitution of generic pharmaceuticals.

9. Demand for prescription pharmaceuticals is not generated by brand or generic pharmaceutical customers (i.e. distributors, wholesalers, retailers, etc.). Demand is created by physicians writing prescriptions for branded or generic products. Demand in the form of prescriptions is satisfied by pharmacists filling prescriptions with FDA approved and regulated

[4] For example, see Gerardi Reply Declaration, paragraph 3j.
[5] Gerardi Reply Declaration, paragraphs 3b and 6.
[6] Gerardi Reply Declaration, paragraph 3g.

specific brand or generic products available at the pharmacy. Pharmacists are not permitted to substitute a different product for a prescribed brand or generic product other than a generic equivalent product without permission from the prescribing physician. The customers of the brand and generic pharmaceutical companies are typically intermediaries (i.e. distributors, wholesalers, or retailers). Detailed information about to whom Lupin sells its products is not necessary for the determination of damages nor is it necessary to ascertain whether Lupin's sales would have been made by Shionogi. The Gerardi Reply Declaration continues to reflect a lack of understanding or appropriate consideration of the market for prescription pharmaceuticals.

10. The Gerardi Reply Declaration claims that customer specific information is needed to quantify lost profits given the different sales channels because, according to Mr. Gerardi, the lost profits available to Shionogi "may be impacted if Lupin received cash sales or made sales to Tier II customers with relatively low co-pays."[7] This statement is incoherent and further reflects the lack of understanding of the market for prescription pharmaceuticals. It is unclear to what the Gerardi Reply Declaration means by "cash sales". If cash sales refers to uninsured patients or the amounts patients pay out of pocket, this has nothing to do with Lupin's sales to its customers (i.e. distributors, wholesales, retailers, etc.) It seems unlikely that "cash sales" refers to Lupin's actual customers since Lupin sells a portfolio of products for millions of dollars to customers. In my experience, large multinational corporations do not pay with or receive cash for such transactions.

11. The reference to "Tier II customers with relatively low co-pays" similarly appears confused and/or unfamiliar with the prescription pharmaceutical market. First, co-pays relate to patients having prescriptions filled at pharmacies. Generic pharmaceutical companies do not sell products directly to patients. The amount a patient is out of pocket for a co-pay has nothing to

[7] Gerardi Reply Declaration, paragraph 3g and 3h.

do with Lupin's sales to its customers. Secondly, the reference to Tier II in the Gerardi Reply Declaration seems to be a reference to formulary coverage. Formularies are maintained by insurance companies, government agencies, and other third party payers ("TPP"). Generic pharmaceutical companies' customers are primarily wholesalers, distributors, and retailers, which generally do not have a formulary (for example, if a generic company sells product either directly or through a distributor to [redacted] the product will be used to fill a prescription for a patient based on the patient's insurance coverage. Neither [redacted] nor the distributor has a formulary). Finally, Tier II formulary status typically covers preferred branded products. Tier I coverage is generally for generic pharmaceutical products, so it is unclear whether the Gerardi Reply Declaration means to refer to Lupin's product being sold as Tier II. The reference to "Tier II customers with relatively low co-pays" demonstrates the lack of understanding and confusion in the Gerardi Reply Declaration regarding the prescription pharmaceutical market.

12. In any event, the suggestion that obtaining customer specific information from Lupin and somehow cross referencing that with Shionogi customer specific information is a reasonable or even feasible method to determine lost profits again reflects a lack of understanding of the prescription pharmaceutical market. The Gerardi Reply Declaration agrees with my description of the complex web of distributors, wholesalers, retailers, mail order companies, and government agencies that are involved in the prescription pharmaceutical market.[8] However, the Gerardi Reply Declaration does not appear to appreciate the impact of the combination of this complex network of intermediary and end user customers with the numerous discounts, rebates, chargebacks, and other incentives that impact sales and profits

[8] Gerardi Reply Declaration, paragraph 3g.

(many of which occur downstream and/or months after the initial sale to a distributor).[9] This combination makes the notion of some sort of specific customer analysis unfeasible. As discussed above, demand is driven by prescription writing, not the distributors, wholesalers, and retailers which are Lupin's customers. Therefore, customer specific information is not needed to determine lost sales by Shionogi.

13. The Gerardi Reply Declaration includes a purported example of why Lupin customer information may be helpful. This simplistic example states that Shionogi may see a decline in sales to a particular customer (such as [redacted] or [redacted]) and that access to Lupin customer information may explain the decline.[10] In my experience, retailers purchase product both directly from pharmaceutical companies as well as from distributors and wholesalers. Many contracts include both a direct price (i.e. purchases from the manufacturer) and an indirect price (i.e. purchases from a distributor or wholesaler). Also, in my experience, generic pharmaceutical companies sell to a combination of distributors, wholesalers, retailers, government agencies and mail order pharmacies. Distributors often purchase months of supply and sell to a variety of customers over time. Once Lupin makes a sale to a particular distributor or wholesaler, the product may be sold to other regional distributors, may be sold to government agencies or mail order pharmacies, or may end up at any of the thousands of pharmacies in the country, reflecting the demand that is driven by prescription writing and not by the customers of

[9] Gerardi Reply Declaration, paragraphs 3g – 3i. For example, product sales to a distributor may occur in a particular period which are then sold to many downstream customers over time. Each downstream customer may have separate contract terms which result in various flow-through discounts, chargebacks, rebates and other incentives which are adjusted over months. Additionally, product return terms vary and occur over time as product becomes short dated or pharmacies identify excess supply. Shelf stock adjustments occasionally occur where companies agree to drop prices in light of price competition. The overly simplistic description of potentially needing customer information for some sort of specific customer analysis demonstrates the lack of understanding of the market for prescription pharmaceuticals in the Gerardi Reply Declaration.

[10] Gerardi Reply Declaration, paragraph 3i.

generic pharmaceutical companies. The overly simplistic example provided in the Gerardi Reply Declaration overstates the need and potential usefulness of Lupin customer information.

14. The Gerardi Reply Declaration suggests that customer specific information is needed to analyze whether Lupin caused the market to expand beyond the Fortamet® market without generic competition.[11] The identity of specific customers, as well as the volumes and prices at which Lupin sold metformin hydrochloride extended release product to specific customers, is not needed and would not be instructive in determining whether the market has expanded beyond the sales of Fortamet® 'but for' generic competition for reasons similar to why the overly simplistic 'customer analysis' suggested in the Gerardi Reply Declaration is unfeasible.

15. Analysis of the overall sales and switches of Fortamet®, generic metformin hydrochloride extended release, Glumetza®, Glucophage® and its generic equivalent products using IMS Health, Inc. ("IMS") data and forecasts from Shionogi and Lupin are the types of information that would be used to analyze the market for Fortamet® and generic metformin hydrochloride extended release to determine whether Shionogi would have made Lupin's sales or if Lupin expanded the market. Initial sales to a wholesaler or distributor often include months worth of inventory. These initial sales do not provide evidence that additional prescriptions are being written or product is being consumed by patients. For this reason, Lupin's sales to specific customers are not necessary to analyze market expansion.

16. The repeated suggestions in the Gerardi Reply Declaration that customer specific information is needed or would be useful in determining damages misapplies the market dynamics for unregulated products where consumer behavior drives demand to prescription pharmaceutical products. As discussed in my previous declaration, in patent cases involving

[11] Gerardi Reply Declaration, paragraph 14.

consumer electronics where the patented feature is but one component of an otherwise complex device with many other attributes, information regarding consumer demand and the importance of the patented features may be needed to determine damages. The FDA regulation of the prescription pharmaceutical market prevents anyone from selling a prescription pharmaceutical product other than a holder of an NDA or ANDA for the brand reference product. Demand for prescription pharmaceutical products is entirely different than demand for consumer electronics. Prescription pharmaceutical products are highly regulated and demand is driven primarily by physician prescribing behavior rather than consumer or intermediary customer behavior.

17. Price erosion is another area where Shionogi and the Gerardi Reply Declaration improperly suggest that customer information from Lupin is needed.[12] In the first instance, no evidence exists that Shionogi has or will lower prices on Fortamet® in response to generic competition.[13] I am unaware of Shionogi claiming or showing that it has actually experienced price erosion or provided discounts for Fortamet® due to the launch by Lupin of metformin hydrochloride extended release product. Not only is there no evidence that Shionogi has experienced price erosion, if there were, the documents required to calculate price erosion damages would come from Shionogi, not Lupin. Shionogi – not Lupin - documents contain the information regarding Fortamet® pricing prior to and after Lupin's launch.

18. In support of the request for information from Lupin, Shionogi's Opposition to Lupin's Motion for a Protective Order makes multiple references to the Kerr and Troxel publication.[14] The Kerr and Troxel publication represents general guidance regarding patent infringement cases and does not address the specific issues in this case or even ANDA litigation

[12] Gerardi Reply Declaration, paragraph 3 and Shionogi's Opposition to Lupin's Motion for a Protective Order, p.9.
[13] Hofmann Declaration, paragraph 19.
[14] Kerr and Troxel publication refers to William O. Kerr & Richard B. Troxel, Calculating Intellectual Property Damages §4.5 (2011). See Shionogi's Opposition to Lupin's Motion for a Protective Order at pp. 1 and 9.

in general. The Kerr and Troxel reference also does not address the issue of balancing the need for information requested in discovery with the potential harm to the producing party of sharing highly confidential information with direct competitors. In fact, the reference to Kerr and Troxel relates only to price erosion, not generally to lost profits or reasonable royalty.[15]

19. The specific citation addresses instances where records of the alleged infringer could be useful in leading to inferences about causation related to price erosion claims.[16] For example, where a patent holder had a history of lowering and raising prices due to a variety of factors beyond competition from the alleged infringer, information from the alleged infringer may provide information as to whether the patent holder lowered the price in response to generic competition. As discussed above, there is no evidence that Shionogi has lowered prices in response to generic competition. Documents and information needed to establish potential price erosion would come from Shionogi and not Lupin.

20. The Gerardi Initial Declaration and the Gerardi Reply Declaration continue to apply the "One Size Fits All" concept to damages discovery in patent infringement cases. I understand that it is appropriate to consider whether information is necessary to determine damages when the information requested is highly confidential and could cause significant harm to the producing party if it were to be shared with direct competitors. Based on my experience in ANDA patent infringement litigation and the information needed to determine damages in such cases, the information requested by Shionogi is overly broad and unnecessary.

[15] William O. Kerr & Richard B. Troxel, Calculating Intellectual Property Damages §4.5 (2011).
[16] William O. Kerr & Richard B. Troxel, Calculating Intellectual Property Damages §4.5 (2011).

Disclosure of Highly Confidential Information to Direct Competitors is Harmful to Lupin

21. Both the Gerardi Reply Declaration and Shionogi's Opposition to Lupin's Motion for a Protective Order suggest that because Lupin relies on confidentiality agreements with its customers, Lupin should not object to producing highly sensitive information under the protective order in this case.[17] The Gerardi Reply Declaration fails to acknowledge or address a critical difference between the customer confidentiality agreements and the protective order in this case—Lupin's confidentiality agreements are with ***customers***, and the protective order would require vast amounts of highly confidential information to be provided to ***direct competitors***. The risk and potential harm to Lupin of providing highly confidential information to direct competitors is far greater than providing limited confidential information to customers with which Lupin has a business relationship. Competitors have strong incentives to act on the information received to the detriment of Lupin.

22. Furthermore, Lupin provides confidential information out of necessity to a particular customer related only to that specific customer. The information requested by Plaintiffs represents highly confidential detailed customer specific information on pricing, sales volume, discounts, rebates and other incentives for *each and every one* of Lupin's customers of metformin hydrochloride extended release.[18] In my experience in the pharmaceutical industry, agreements with customers are often covered by master agreements which involve a portfolio of products.[19] Therefore, if Lupin is required to produce the requested information, a direct competitor could be given Lupin's pricing, discounts and incentives to all of its customers, allowing them to understand Lupin's entire pricing strategy for numerous products.

[17] Paragraph 12 of the Gerardi Reply Declaration and p. 16 of Shionogi's Opposition to Lupin's Motion for a Protective Order

[18] Lupin's customers would already be well aware of their own individual pricing, purchasing, discounts, etc.

[19] My understanding is consistent with the Declaration of Robert G. Hoffman, dated October 20, 2011 at paragraph 9.

23. Exposure of Lupin's pricing strategies for metformin hydrochloride extended release could cause significant harm regarding this product as well as numerous other Lupin products due to the competitive nature of the pharmaceutical market. The Gerardi Reply Declaration fails to acknowledge the major differences between customer confidentiality agreements used by Lupin in the normal course of business and the protective order in this litigation among direct competitors, resulting in inappropriate conclusions. However, the Gerardi Reply Declaration does acknowledge the highly sensitive nature of the competition among the parties in this case:

- *I understand that the products accused of infringement in this matter are regulated, and that the dynamic of competition among branded and generic companies and competition between generic companies may result in "heightened commercial sensitivity" of highly confidential information.*[20]

24. The Plaintiffs claim that Lupin has not identified or provided specific examples of how Lupin will be harmed by disclosing this highly confidential information.[21] The Declaration of Robert G. Hoffman, dated October 20, 2011 demonstrated how Lupin will be harmed if confidential information is obtained by Lupin's competitors.

- [redacted]
- [redacted]
- [redacted]

[20] Gerardi Reply Declaration at paragraph 10c.
[21] Shionogi's Opposition to Lupin's Motion for a Protective Order, p. 17.

[redacted]

[redacted]

25. As I discussed in my previous declaration, Plaintiffs in this matter include the Andrx family of companies including Andrx Pharmaceuticals Inc. (N/K/A Watson Laboratories, Inc. – Florida), a subsidiary of Watson Pharmaceuticals, Inc. ("Watson"), a generic pharmaceutical company. Watson is one of the largest generic pharmaceutical companies in the world and will become the third largest generic pharmaceutical company with the recently announced acquisition of Actavis Group.[26] Generic pharmaceutical companies compete vigorously on price. If Andrx obtains Lupin's pricing and other customer specific information, it may be able to take sales from Lupin of its generic metformin hydrochloride extended release product, as well as other pharmaceutical products not involved in this litigation. Disclosure of this information to competitors is likely to cause Lupin harm across customers and product portfolios by allowing the competitor to undercut Lupin's price on several products, not just its metformin hydrochloride extended release product.

26. The Plaintiffs suggest that Lupin is resisting production of certain documents because the documents are unhelpful to Lupin.[27] My opinions contained within this and my previous declaration, are based on the information which is *necessary*, not whether the

[redacted]

[26] Watson Pharmaceuticals' Press Release, dated April 25, 2012 at http://ir.watson.com/phoenix.zhtml?c=65778&p=irol-newsArticle&ID=1687367&highlight= (accessed May 3, 2012).

[27] Shionogi's Opposition to Lupin's Motion for a Protective Order, p. 16.

[redacted]

information is helpful or unhelpful to Lupin.[28] The purpose of the Hofmann Declaration and this declaration is to determine whether certain requested documents are necessary to determine damages balanced with the potential harm that could be caused to Lupin if such information is produced to direct competitors.

[redacted]

[28] [redacted]

[29] [redacted]

[redacted]

[redacted]

[redacted]

Documents Needed for an Analysis of Commercial Success and Nexus

36. Shionogi's Opposition to Lupin's Motion for a Protective Order and the Plaintiffs' Answering Brief in Opposition to Defendants' Motion to Bifurcate Liability and Damages and to Stay Damages Discovery discuss documents and information that Plaintiffs alleges may be relevant to analysis of secondary considerations of nonobviousness, such as commercial success and nexus.[33] The Gerardi Initial Declaration and Gerardi Reply Declaration are silent on this issue. The analysis of commercial success in this matter is to determine whether the branded pharmaceutical product is commercially successful and if so, whether such commercial success (if any) is due to the unique claimed features of the patent (i.e. nexus). In my experience in ANDA litigation, the primary documents and information that are needed for analysis of commercial success and nexus come from branded pharmaceutical company records and third party data and are generally different from the detail needed for a damages analysis.

37. A commercial success inquiry typically focuses on the performance of the branded product prior to generic competition. From an economic perspective, this is typically the relevant period since price competition following generic competition diminishes sales of the

[redacted]

[33] Shionogi's Opposition to Lupin's Motion for a Protective Order, pp.13 and 14 and Plaintiffs' Answering Brief in Opposition to Defendants' Motion to Bifurcate Liability and Damages and to Stay Damages Discovery at p.5.

brand product irrespective of any prior commercial success due to claimed features of the patent (if any). One can analyze the sales and profitability performance of the branded product prior to generic competition, understand the performance relative to competing branded products, analyze pricing and formulary coverage, and evaluate other factors, from the brand company's information and documents. Furthermore, the performance of a generic product is generally not instructive to the potential commercial success of a branded product since the generic product typically enters the market and achieves sales through substitution and/or migration from other branded and generic products, primarily due to lower generic prices.

38. A nexus inquiry examines whether factors other than the claimed features of the patent led to any commercial success (i.e. features not claimed in the patent, overall market growth, heavy sales and marketing efforts, discounts and incentives on the branded product, etc.). Given that a commercial success and nexus analysis primarily focuses on the performance of the brand product prior to generic competition, the information required to undertake such an analysis is typically produced from the branded company's records (marketing documents, business plans, market studies, sales and profitability information, etc.) and third party data (i.e. IMS, Fingertip Formulary, etc.)[34]

39. Given the 30 month stay under the Hatch-Waxman Act which prevents the generic from launching in ANDA litigation, the majority of commercial success analyses are performed prior to the existence of generic competition for the branded product. Therefore, most commercial success inquiries are undertaken with minimal generic documents or information regarding generic sales.

[34] IMS is a company that aggregates pharmaceutical product information through surveys, inquiries, and sampling to provide sales, marketing costs, prescribing behavior, and other information for the pharmaceutical industry. Fingertip Formulary is a company that aggregates formulary status, tier status and coverage data for various pharmaceutical products. Other third party data sources regarding the pharmaceutical industry exist in the public domain and through subscription services.

40. Lupin's launch of its generic metformin hydrochloride extended release product in this matter, does not change the relevant inquiry, since the focus is on the performance of the branded product. Therefore, production of additional Lupin documents is not necessary to analyze commercial success in this case. Likewise, for all of the reasons outlined in this and my previous declaration, additional Lupin documents including those involving specific customer information are not necessary for the determination of damages.

41. [redacted]

42. Analysis of commercial success and the calculation of alleged damages are performed for different reasons and produce different results. Analysis of commercial success is based on the market for the branded product and on analyzing a variety of indicators of potential commercial success as well as determining whether nexus exists between the patent-in-suit and any such commercial success. The initial step of a commercial success inquiry is to determine whether a product is commercially successful. If the product is not a commercial success, then the performance of the brand product provides no objective indicia of nonobviousness.

43. If the product is determined to be commercially successful, analysis is performed to determine whether the alleged commercial success is due to the unique claims of the patent.

[redacted]

Factors considered in analyzing commercial success include performance relative to other products in the market, marketing information, physician studies and survey data, and other information, most of which comes from third party data and the branded company.

44. In my experience in ANDA litigation, the analysis and testimony regarding commercial success and nexus is very different from the analysis and testimony regarding the determination of damages. Similarly, the primary information used to analyze commercial success and nexus is generally not needed for the determination of damages. A commercial success and nexus inquiry is much more qualitative than the calculation of damages, which is much more quantitative. Commercial success and nexus involve issues to assist in determining whether a patent is invalid due to obviousness whereas analysis of damages assumes that the patent is valid and infringed.

Conclusion

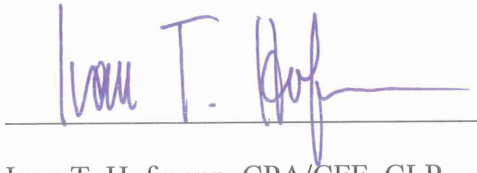
45. In my experience in ANDA patent infringement litigation, the production of documents with respect to damages and commercial success by the branded and generic pharmaceutical companies is typically asymmetric (i.e. where the production by the branded company is much greater than the production by the generic company, both in terms of volume and types of information). The determination of lost profits and reasonable royalty is largely based on documents from the Plaintiff, who has been selling the branded product for some time. Similarly, the information used to analyze secondary considerations of nonobviousness, such as commercial success and nexus, is largely based on sales and marketing documents, surveys, business plans, IMS data, formulary information, and other such information which is typically produced by the branded company or available from third parties.

46. I understand that Lupin has agreed to produce certain information, including net sales and units sold of Lupin's metformin hydrochloride extended release product, by dosage strength, as well as Lupin's forecasts and projections for metformin hydrochloride extended release. In conjunction with information and documents in Shionogi's possession, the information Lupin has agreed to produce is sufficient to analyze damages as well as commercial success in this case. In any event, the Lupin customer specific information requested by Shionogi would not be necessary to analyze damages or commercial success in this matter.

I, Ivan T. Hofmann, hereby declare, under penalty of perjury under 28 U.S.C. § 1746 and the laws of the United States of America, that the foregoing Declaration is true and correct.

Date: May 7, 2012

Redacted Version Filed May 29, 2012



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